

## **II. REMARKS/ARGUMENTS**

### **A. Status of the Claims**

Claims 54 and 57 were amended without prejudice or admission. Support for the amendments can be found, e.g., on page 22, lines 8-15, of the original specification.

Applicants respectfully submit that no new matter was added by virtue of the present amendments.

Claims 38, 47 and 53-64 are pending and are encompassed by the elected invention, including the elected species.

### **B. Claim Rejections- 35 U.S.C. § 103**

#### **1. Baker et al. (U.S. Patent No. 4,569,937) in view of the Furst article, Oshlack I et al. (U.S. Patent No. 5,472,712), Oshlack II (U.S. Patent No. 6,294,195) and Iyengar et al. (WO 97/25988)**

Claims 38, 47, 48, 53, and 54 were rejected under 35 U.S.C. § 103(a) over Baker et al. (U.S. Patent No. 4,569,937) in view of Furst (Furst, D.E. "Meloxicam: Selective COX-2 inhibition in clinical practice" Seminars in Arthritis and Rheumatism, June 1997, 26(1), 21-27) and in further view of Oshlack I et al. (U.S. Patent No. 5,472,712) and/or Oshlack II (U.S. Patent No. 6,294,195) and Iyengar et al. (WO 97/25988).

The rejection is respectfully traversed for the reasons presented in the response filed on April 1, 2009, hereby incorporated by reference, and the reasons given below.

Independent claim 38 is directed in part to a method of treating pain by administering meloxicam in combination with oxycodone to a human patient as recited in the claim 38.

Applicants respectfully submit that the combination of the cited references does not teach or suggest administering meloxicam together with oxycodone, e.g., because the Furst article (which was relied upon by the Examiner for the teaching of meloxicam) describes administration of meloxicam by itself, without any additional analgesic agents. Applicants further submit that there is nothing in the cited references that indicates that administration of meloxicam by itself will not provide adequate analgesia.

In response to the Examiner's statement on page 6 of the Office Action that Iyengar et al. states that "[t]he present invention encompasses ... Meloxicam" in paragraph bridging pages 46 and 47, Applicants respectfully note that the Iyengar reference describes methods of treating pain by administering "a tachykinin receptor antagonist" (i.e., a compound of Formula I described therein) in combination with an analgesic (e.g., meloxicam) whose primary mechanism of action is not a tachykinin receptor antagonist and "pharmaceutical formulations comprising a compound of formula (I) in combination with a traditional analgesic." See, e.g., Abstract. Accordingly, Applicants respectfully submit that any method or formulation in accordance with the teachings of the Iyengar reference will necessarily include the compound of Formula I.

The compound of Formula I is however excluded from the scope of claim 38, by virtue of "consisting of" language recited the claim. Applicants respectfully note that oxycodone is not encompassed by the structure of the compound of Formula I. See, e.g., structure of oxycodone provided on page 46 of the Iyengar reference.

Accordingly, Applicants submit that the combination of the Iyengar reference with the Baker patent, the Furst Article, and the Oshlack patents cannot render the method of claim 38 obvious.

In addition, Applicants submit that there is nothing in the cited references that suggest incorporation of meloxicam into an oral dosage form comprising "a sustained release carrier in an amount such that said oral dosage form provides a therapeutic effect for about 12 hours."

In response to the Examiner's statement starting on page 10 of the Office Action "that the FDA's position concerned inconclusive pharmacology and endoscopy evidence regarding ... Meloxicam being more selective for COX-2 over COX-1 ... as opposed to Meloxicam failing to show any selectivity whatsoever, as alleged by applicant," Applicants respectfully clarify that they did not allege that Meloxicam fails to show any selectivity, rather Applicants submitted that "the FDA could not conclude, based on the data generated prior to March 27, 2000, that meloxicam had less serious GI adverse events than other NSAIDs (e.g., ibuprofen)." See Response filed on April 1, 2009, page 9.

For the foregoing reasons, withdrawal of the rejection is respectfully requested.

**2. Baker et al. (U.S. Patent No. 4,569,937) in view of the Furst article, Oshlack I et al. (U.S. Patent No. 5,472,712), Oshlack II (U.S. Patent No. 6,294,195) and Ivengar et al. (WO 97/25988), Eichel et al. (U.S. Patent No. 5,376,384) and Miller et al. (EP 0649657)**

Claims 38, 47, 48, 53-64 were rejected under 35 U.S.C. § 103(a) over Baker et al. (U.S. Patent No. 4,569,937), Furst (Furst, D.E. "Meloxicam: Selective COX-2 inhibition in clinical practice" Seminars in Arthritis and Rheumatism, June 1997, 26(1), 21-27), Oshlack I et al. (U.S. Patent No. 5,472,712), Oshlack II (U.S. Patent No. 6,294,195), Ivengar et al. (WO 97/25988), Eichel et al. (U.S. Patent No. 5,376,384) and Miller et al. (EP 0649657). The Eichel and Miller references were relied upon by the Examiner for the teaching of "an immediate-release form used in conjunction with a sustained release form." Office Action, page 14.

The rejection is respectfully traversed, for the reasons presented in the response filed on April 1, 2009, hereby incorporated by reference, and the reasons given below.

Applicants respectfully submit that the combination of the Baker patent, the Furst article, Oshlack I patent, Oshlack II patent and the Iyengar patent does not teach or suggest a method of treating pain by administering to a human patient meloxicam in combination with oxycodone as recited in claims 38 and 55 for the reasons given above.

Applicants further submit that the Eichel and Miller references cannot cure this deficiency, as they do not describe administration of meloxicam in combination with any additional analgesic agents, let alone oxycodone as recited in claims 38 and 55.

Accordingly, Applicants submit that the combination of the cited references does not render claims 38 and 52 and their dependent claims obvious.

With further regard to claims 63 and 64, Applicants submit that the combination of the cited references does not teach or suggest administering meloxicam twice-a-day, at the very least because the reference relied upon for the teaching of meloxicam (i.e., the Furst reference) describes administration of meloxicam once-a-day. Applicants therefore submit that the combination of the cited references does not render claims 63 and 64 obvious for this additional reason.

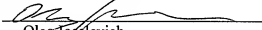
For the foregoing reasons, withdrawal of the rejection is respectfully requested.

**III. CONCLUSION**

An early and favorable action on the merits is earnestly solicited. The Examiner is respectfully requested to contact the undersigned at the telephone number provided below in the event that a telephonic interview will advance the prosecution of the application.

Respectfully submitted,

DAVIDSON, DAVIDSON & KAPPEL, LLC

By:   
Oleg Ioselevich  
Reg. No. 56,963

DAVIDSON, DAVIDSON & KAPPEL, LLC  
Patents, Trademarks and Copyrights  
485 Seventh Avenue, 14<sup>th</sup> Floor  
New York, New York 10018  
(212) 736-1940